

Cardioprotective Haemodialysis

## 4008S classix

Quality treatment to suit your budget



Cardioprotective Haemodialysis **SPOT**

# Protect your Patient

## Cardioprotective Haemodialysis

The reduction of risk factors for cardiovascular diseases (CVD) is core to the development of dialysis systems and products at Fresenius Medical Care. Outstanding cardioprotection must be reflected in all levels of product development and application.

## Wide-ranging cardioprotection

There have been tremendous improvements in the quality and efficacy of haemodialysis (HD) therapy in recent years. Despite this, cardiovascular diseases (CVD) remain the leading cause of death for patients with end-stage renal disease (ESRD).

# SP

# Cardioprotective

## Services

Over 30 years of experience in dialysis at your service.

- Project Planning and Consulting
- Training and Education
- Technical Services
- Water Quality Service (WQS)
- Medical Information Services

## Products

State-of-the-art technologies enable advanced cardioprotective therapies.

- CorDiax product line:
  - 5008 CorDiax and 5008S CorDiax
  - FX CorDiax haemodiafilter
  - BCM-Body Composition Monitor
- Classix product line:
  - 4008S classix
  - FX classix dialysers
- Therapy Data Management System (TDMS)
- Online Purification Cascade (OPC)

Moreover, both overall and cardiovascular mortality are markedly greater in ESRD patients than in the general population. This is why we put Cardioprotective Haemodialysis on the SPOT. A comprehensive approach that includes services, products and therapies is needed to

achieve the best therapeutic performance – meaning improved clinical outcomes and better quality of life, enhanced control of therapy costs, and simpler, safer handling.



# Haemodialysis

## Outcomes

Achieving better outcomes with cardioprotective therapies.

- Reduced mortality risk
- Fewer cardiovascular complications
- Optimised use of resources

## Therapies

Cardioprotective therapies designed by the world market leader in haemodialysis.

- High-Flux dialysis
- HighVolumeHDF®
- Advanced Fluid Management

# Protect your Patient

## Cardioprotection – at the heart of long-term haemodialysis

Both, chronic kidney disease (CKD) and dialysis itself can lead to cardiovascular alterations such as atherosclerosis and left ventricular hypertrophy (LVH). Even though the quality and efficacy of haemodialysis therapy have greatly improved in recent years, cardiovascular disease (CVD) remains the leading cause of death in haemodialysis patients.

Fresenius Medical Care's mission is to enable nephrologists to provide the best possible therapy for their long-term haemodialysis patients, in order to minimise the risk of CVD.

We strive to continuously refine and develop new dialysis therapies and products to improve the clinical outcomes of dialysis patients. We set the standards for both convective therapies and standard haemodialysis as we are fully aware of our responsibility to provide high quality treatment no matter if HDF or HD.

The 4008S classix allows you to utilise the benefits of Cardioprotective Haemodialysis and continues the outstanding success of the 4008 series.

It combines technological enhancement with a clear emphasis on delivering the highest quality HD treatment, while maintaining its proven reliability and cost-efficiency. The 4008S classix fulfils this promise with its fundamental features:

- Online assessment of dialysis efficiency and dose (OCM<sup>®</sup>)
- Ultrapure dialysis fluid (DIASAFE<sup>® plus</sup>)
- Hygienic dry bicarbonate concentrate supply (bibag<sup>®</sup>)





# SPOT

SPOT on:

Cardioprotective  
Haemodialysis set  
as standard by:

- OCM®
- DIASAFE® plus
- bibag®

# Protect your Patient

## Assuring quality in operations

### Operational efficiency

Haemodialysis involves a large number of demanding manual operations all around the haemodialysis machine. The ergonomic design and the logical operating structure of the 4008S classix permit easy handling as well as fast and intuitive programming of the treatment parameters. Important treatment values are represented graphically on the 10.4" TFT-LCD monitor, which supports easy comprehension of the ongoing treatment, and provides a fast overview of the treatment history. The Blood Pressure Monitor (BPM) is fully integrated, which further simplifies handling for the therapy providers.

In combination with the Therapy Data Management System (TDMS) daily dialysis practice can be organised in a more effective and efficient manner taking full advantage of an online data acquisition and management tool.

### OCM<sup>®</sup> – Online Clearance Monitor

In the meantime numerous studies have demonstrated that morbidity and mortality rates are closely correlated to the delivered dialysis dose. <sup>1,2</sup>

The Online Clearance Monitor (OCM<sup>®</sup>) enables the continuous monitoring of:

- The effective in-vivo urea clearance (K)
- The accumulated cleared plasma (Kt) or the current dialysis dose administered (Kt/V)
- The plasma sodium concentration: possible deviations to the prescribed therapy goal can be detected and corrected immediately during treatment\* without incurring additional expenses for disposables or staff efforts

The non-invasive and precise Kt/V assessment is consistent with conventional blood sample-based methods enabled by urea distribution volume V measured with the BCM-Body Composition Monitor. <sup>3</sup>

\* OCM measurement is not possible in Single needle and ISO-UF mode



► Settings for Blood Pressure Monitor (BPM)



► Settings for Online Clearance Monitor (OCM<sup>®</sup>)

## Delivering quality in therapy

### DIASAFE® *plus* – Dialysis Fluid Filter

The quality and purity of the dialysis fluid are of major concern in modern-day renal replacement therapies, as large volumes of dialysis fluid come into contact with the patient's bloodstream during each treatment. Endotoxins present in contaminated dialysis fluid may elicit undesirable acute reactions and influence the long-term outcome of patients on chronic haemodialysis.

The DIASAFE® *plus* dialysis fluid filter enables the safe production of ultrapure dialysis fluid. This is attributed to the excellent endotoxin-retention capabilities of its Fresenius Polysulfone® fibres and an intelligent safety concept, based on:

- Functional control of filter integrity
- Automatic surveillance of filter lifetime
- Aseptic connection technology

Ultrapure dialysate fluid is acknowledged to be an integral part of all contemporary dialysis equipment.

Naturally the DIASAFE® *plus* is an essential part of the basic configuration of all current Fresenius Medical Care dialysis machines.



▶ DIASAFE® *plus* – Dialysis Fluid Filter

### bibag® – Dry Bicarbonate Concentrate

To avoid the potential risk of microbiological contamination through liquid bicarbonate concentrate, the bicarbonate buffer is always supplied as a dry substance.

In addition to this excellent hygienic standard, the bibag® is characterised by:

- Easy and ergonomic handling
- Minimum storage space required
- Ecological benefits due to reduced waste volume and less transport weight

1. Hakim R, Breyer J, Ismail N, Schulmann G: Effects of dose of dialysis on morbidity and mortality. *Am J Kidney Dis* (1994); 23:661-669
2. Port F, Ashby V, Dhingra R, Roys E, Wolfe R: Dialysis dose and body mass index are strongly associated with survival in hemodialysis patients. *J Am Soc Nephrol* (2002); 13:1061-1066
3. Lindley EJ, Chamney PW, Wuepper A, Ingles H, Tattersall JE, Will EJ: A comparison of methods for determining urea distribution volume for routine use in on-line monitoring of haemodialysis adequacy. *Nephrol Dial Transplant* (2009); 24(1):211-6



▶ bibag® – Dry Bicarbonate Concentrate

# Protect your Patient

## Quality treatment to suit your budget

Almost one in two patients with ESRD dies as a result of cardiovascular disease. That is why Cardioprotective Haemodialysis is a core principle of Fresenius Medical Care, as we work and strive to solve the challenges of modern dialysis. Each step we take is focused on minimising cardiovascular risks and extending patients' lives. The 4008S classix continues the success story of the well known 4008 series, by combining best quality HD treatment, proven reliability and operational efficiency.







### Proven quality

The latest member of a long established and highly successful 4008 series

- Advanced dialysis fluid circuit with highly-precise volumetrically controlled ultrafiltration
- Consistently reliable hydraulics



### Advanced treatment

High-quality HD treatment to protect your patient

- OCM<sup>®</sup> (Online Clearance Monitor)
- DIASAFE<sup>® plus</sup> (Dialysis Fluid Filter)
- bibag<sup>®</sup> (Dry Bicarbonate Concentrate)
- Single needle or SN Click-Clack
- ISO-UF programme



### Operational efficiency

Cost effective use of resources

- Easy, fast and intuitive handling
- TDMS (Therapy Data Management System)
- BPM (Blood Pressure Monitor)
- CDS (Central Concentrate Delivery System)

# Protect your Patient



## Proven quality

The latest member of a long established and highly successful 4008 series



## Advanced treatment

High-quality HD treatment to protect your patient



## Operational efficiency

Cost effective use of resources



General data	
<b>Dimensions 4008S</b>	1370 x 500 x 650 mm (H x W x D) (including shunt interlock and pedestal)
<b>Weight</b>	approx. 86 kg
<b>Water supply</b>	
Water inlet pressure	1.5 to 6.0 bar
Water inlet temperature	5°C to 30°C; for "integrated hot rinse" 85°C to 95°C
Max. drain height	1 m
<b>Concentrate supply</b>	
Supply pressure	0 to 100 mbar; 1 m max. suction height
<b>Central supply</b>	1 central acid concentrate (optional) 0 to 500 mbar
<b>Electrical data</b>	
Power supply	100 to 240 V AC, 50 to 60 Hz
Current consumption	Approx. 9 A (at 230 V) and 15 A (at 110 V)
<b>External connections</b>	Network interface for data exchange with Therapy Data Management System (optional); input/output for connection of external auxiliary equipment; alarm input/output (e.g. for nurse call); diagnosis for in-house computer diagnosis
<b>Battery</b>	18 V; 3 Ah (maintenance free)
Extracorporeal circuit	
<b>Arterial pressure monitoring</b>	
Display range	- 300 mmHg to + 280 mmHg
Accuracy	±10 mmHg
Resolution	20 mmHg
<b>Venous pressure monitoring</b>	
Display range	- 60 mmHg to + 520 mmHg
Accuracy	±10 mmHg
Resolution	20 mmHg
<b>Transmembrane pressure monitoring</b>	
Display range	- 60 mmHg to + 520 mmHg
Resolution	20 mmHg
<b>Arterial blood pump</b>	
Blood flow range	15 to 600 mL/min
Accuracy	± 10%
Resolution	5 mL/min
<b>Single needle system (optional)</b>	With 2 blood pumps, internal pressure/pressure control with variable stroke volume (max. 50 mL/min)
<b>Air bubble detector</b>	Ultrasonic transmission measurement on blood line, additional optical monitoring in venous clamp
<b>Heparin pump</b>	Delivery range: 0 to 10 mL/h Bolus function: max. 5 mL per bolus Syringe size: 20 mL
Dialysis fluid circuit	
<b>Dialysis fluid flow range</b>	
Selectable	0 – 300 – 500 – 800 mL/min
AdaptedFlow* (selectable)	Dialysate flow adapted to the effective blood flow
<b>Dialysis fluid temperature</b>	
Selectable	35°C to 39°C
<b>Dialysis fluid conductivity</b>	
Range	12.8 to 15.7 mS/cm (25°C)
Accuracy	± 0.1 mS/cm
Resolution	0.1 mS/cm

<b>Dialysis fluid acid component</b>	
Mixing ratio	Adjustable, e.g. 1+44, 1+34
Adjustment range	125 to 150 mmol/L
<b>Dialysis fluid bicarbonate component</b>	
Default mixing ratio	1 + 27.6 (others possible)
Adjustment range	- 8 to + 8 mmol/L
<b>OCM®</b>	Online Clearance Monitoring
Accurate Clearance K	± 6%
<b>Bicarbonate dry concentrate</b>	bi/bag®
<b>Dialysis fluid filter system</b>	DIASAFE® plus
<b>Balancing accuracy</b>	
Pressure holding tests	± 0.1 % according to the total dialysate volume Cyclic
<b>Ultrafiltration</b>	
UF rate	0 to 4000 mL/h (in steps of 1 mL/h)
Pump volume accuracy	± 1%
Parameters displayed	UF goal, UF time, UF rate, UF volume
<b>Blood leak detector</b>	
Sensitivity	≤ 0.5 mL blood/min (Hct = 25) at max. flow 800 mL/min
<b>BPM (optional)</b>	
Display range	Systole: 30 mmHg to 280 mmHg Diastole: 10 mmHg to 240 mmHg MAP: 20 mmHg to 255 mmHg Pulse: 20 to 245 1/min
Accuracy	± 3 mmHg
Resolution	1 mmHg
Disinfection and cleaning programmes**	
<b>Rinse</b>	
Temperature/flow	37 °C / 600 mL/min
<b>Hot rinse (recirculation)</b>	
Temperature/flow	84 °C / 450 mL/min
<b>Integrated hot rinse</b>	
Temperature/flow	84°C / 450 mL/min
<b>Cleaning Sporotal®100 (recirculation)</b>	
Temperature/flow	37 °C / 600 mL/min
<b>Heat disinfection Diasteril®/Citrosteril® (recirculation)</b>	
Temperature/flow	84° C / 450 mL/min
<b>Disinfection Puristeril® 340/plus (recirculation)</b>	
Temperature/flow	37 °C / 600 mL/min

\* Not available in all countries.

\*\* Various programme combinations selectable.  
Technical changes reserved.



**FRESENIUS  
MEDICAL CARE**

Head office: Fresenius Medical Care Deutschland GmbH · 61346 Bad Homburg · Germany  
Phone: +49 (0) 6172-609-0 · Fax: +49 (0) 6172-609-2191  
[www.fmc-ag.com](http://www.fmc-ag.com)